

PATENT COOPERATION TREATY

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

Commissioner
 US Department of Commerce
 United States Patent and Trademark
 Office, PCT
 2011 South Clark Place Room
 CP2/5C24
 Arlington, VA 22202
 ETATS-UNIS D'AMERIQUE

in its capacity as elected Office

Date of mailing (day/month/year) 13 November 2000 (13.11.00)	Applicant's or agent's file reference 82 073 a/sk
International application No. PCT/EP00/02910	Priority date (day/month/year) 01 April 1999 (01.04.99)
International filing date (day/month/year) 31 March 2000 (31.03.00)	
Applicant GERDES, Johannes et al	

1. The designated Office is hereby notified of its election made:

☒ in the demand filed with the International Preliminary Examining Authority on:

24 October 2000 (24.10.00)

☐ in a notice effecting later election filed with the International Bureau on:2. The election ☒ was☐ was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No.: (41-22) 740.14.35	Authorized officer Nestor Santesso Telephone No.: (41-22) 338.83.38
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From the INTERNATIONAL BUREAU

PCT

**NOTIFICATION OF THE RECORDING
OF A CHANGE**

(PCT Rule 92bis.1 and
Administrative Instructions, Section 422)

To:

KOLB, Helga
Hoffmann . Eitle
Arabellastrasse 4
D-81925 Munich
ALLEMAGNE

Date of mailing (day/month/year)

01 November 2001 (01.11.01)

Applicant's or agent's file reference

82 073 a/sk

IMPORTANT NOTIFICATION

International application No.

PCT/EP00/02910

International filing date (day/month/year)

31 March 2000 (31.03.00)

1. The following indications appeared on record concerning:



the applicant



the inventor



the agent



the common representative

Name and Address

FORSCHUNGSZENTRUM BORSTEL
Parkallee 1-40
D-23845 Borstel
Germany

State of Nationality

DE

State of Residence

DE

Telephone No.

Facsimile No.

Teleprinter No.

2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning:



the person



the name



the address



the nationality



the residence

Name and Address

DAKO A/S
Produktionsvej 42
DK-2600 Glostrup
Denmark

State of Nationality

DK

State of Residence

DK

Telephone No.

Facsimile No.

Teleprinter No.

3. Further observations, if necessary:

4. A copy of this notification has been sent to:



the receiving Office



the International Searching Authority



the International Preliminary Examining Authority



the designated Offices concerned



the elected Offices concerned



other:

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Facsimile No.: (41-22) 740.14.35

Authorized officer

N. Wagner

Telephone No.: (41-22) 338.83.38

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 82 073 a/sk	FOR FURTHER ACTION see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.	
International application No. PCT/EP 00/ 02910	International filing date (day/month/year) 31/03/2000	(Earliest) Priority Date (day/month/year) 01/04/1999
Applicant FORSCHUNGSZENTRUM BORSTEL et al.		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 5 sheets.



It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

- a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.



the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

- b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing :



contained in the international application in written form.



filed together with the international application in computer readable form.



furnished subsequently to this Authority in written form.



furnished subsequently to this Authority in computer readable form.



the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.



the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. ☒ **Certain claims were found unsearchable** (See Box I).

3. ☒ **Unity of invention is lacking** (see Box II).

4. With regard to the **title**,



the text is approved as submitted by the applicant.



the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,



the text is approved as submitted by the applicant.



the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is Figure No.



as suggested by the applicant.



because the applicant failed to suggest a figure.



because this figure better characterizes the invention.

1



None of the figures.

INTERNATIONAL SEARCH REPORT

International Application No

PCT/EP 00/02910

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 C07K16/18 C12N5/16 C12N5/18 G01N33/53 A61K39/395

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 C07K C12N G01N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	HU B ET AL: "The P1 family: a new class of nuclear mammalian proteins related to the yeast Mcm replication proteins." NUCLEIC ACIDS RESEARCH, (1993 NOV 25) 21 (23) 5289-93., XP000941330 cited in the application page 5289, right-hand column page 5290	1-24
A	--- SOMEYA A ET AL: "The possible involvement of replication-related proteins with a DEAD-box-like motif in cell-free DNA replication of Xenopus eggs." BIOCHEMICAL AND BIOPHYSICAL RESEARCH COMMUNICATIONS, (1995 JUL 26) 212 (3) 1098-106., XP000941401 the whole document --- -/--	1-24



Further documents are listed in the continuation of box C.



Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search

24 October 2000

Date of mailing of the international search report

14.12.00

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Mennessier, T

PCT/EP 00/02910

Category °

Citation of document, with indication, where appropriate, of the relevant passages

Relevant to claim No.	
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A

THOMMES P ET AL: "Properties of the
nuclear P1 protein, a mammalian homologue
of the yeast Mcm3 replication protein."
NUCLEIC ACIDS RESEARCH, (1992 MAR 11) 20
(5) 1069-74., XP002150915
cited in the application
the whole document

1-24

INTERNATIONAL SEARCH REPORT

International application No.
PCT/EP 00/02910

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

Although claim 24 is directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the composition.
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

1-22 and 24

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

1. Claims: 1-22 and 24

Claims 1-5 which are each directed to an anti-human Mcm3 monoclonal antibody.

Claims 6-7 which are each directed to a hybridoma secreting such an antibody.

Claims 8-14 which are each directed to the use of such an antibody in a detection method for human Mcm3.

Claims 15-18 which are each directed to a process for the production of such an antibody.

Claim 19 which is directed to diagnostic composition comprising such an antibody.

Claim 20 which is directed to the use of such an antibody for the production of therapeutical preparations.

Claim 21 which is directed to a pharmaceutical preparation comprising such antibodies.

Claim 22 which is directed to a diagnostic kit comprising such an antibody.

Claim 24 which is directed to a method of preventing or treating a disease involving the administration of such an antibody.

2. Claim : 23

Claim 23 which is directed to a diagnostic kit for the combined detection of the "expression" of Mcm3, Ki-67 and p27.



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁷ : C07K 16/18, C12N 5/16, 5/18, G01N 33/53, A61K 39/395		A2	(11) International Publication Number: WO 00/59943
			(43) International Publication Date: 12 October 2000 (12.10.00)
(21) International Application Number: PCT/EP00/02910 (22) International Filing Date: 31 March 2000 (31.03.00) (30) Priority Data: 199 15 057.5 1 April 1999 (01.04.99) DE (71) Applicant (for all designated States except US): FORSCHUNGSZENTRUM BORSTEL [DE/DE]; Parkallee 1-40, D-23845 Borstel (DE). (72) Inventors; and (75) Inventors/Applicants (for US only): GERDES, Johannes [DE/DE]; Steinfeld 79, D-23858 Feldhorst (DE). SCHOLZEN, Thomas [DE/DE]; Herrenweg 3, D-23843 Neritz (DE). ENDL, Elmar [DE/DE]; Kupferleichweg 22, D-22399 Hamburg (DE). WOHLBERG, Claudia [DE/DE]; Kupferleichweg 22, D-22399 Hamburg (DE). BARON-LUHR, Bettina [DE/DE]; Ehlers 13, D-23815 Westerade (DE). HAHN, Margrit [DE/DE]; Parkallee 40a, D-23845 Borstel (DE). PRILLA, Patricia [DE/DE]; Stresemannstrasse 128, D-22769 Hamburg (DE). SZUWINSKI, Johanna [DE/DE]; Beckertwiete 1, D-24649 Wiemersdorf (DE). KNIPPERS, Rolf [DE/DE]; Koberleweg 17, D-78464 Konstanz (DE).		(74) Agents: KOLB, Helga et al.; Hoffmann . Eitle, Arabellastrasse 4, D-81925 Munich (DE). (81) Designated States: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG). Published Without international search report and to be republished upon receipt of that report.	
(54) Title: MONOCLONAL ANTIBODIES AGAINST HUMAN PROTEIN Mcm3, PROCESS FOR THEIR PRODUCTION, AND THEIR USE			
(57) Abstract			
<p>The present invention relates to monoclonal antibodies against the human Mcm3 protein, hybridoma cell lines, that produce such antibodies, procedures for the production and their use, pharmaceutical compositions comprising a monoclonal antibody according to the present invention, their use for the prevention and treating of certain diseases and well of methods relating to the prevention and treatment of diseases associated with Mcm3 expression. Monoclonal antibodies according to the invention detect and bind human Mcm3 monospecifically both in immunohistological and immunobiochemical detection systems. The process for the production of these monoclonal antibodies comprises an initial screening of excess hybridoma supernatant with immunobiochemical methods followed by a second screening of positive hybridoma by means of an immunohistochemical method.</p>			

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
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DK	Denmark	LR	Liberia	SG	Singapore		
EE	Estonia						



Published:

— With international search report.


For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(88) Date of publication of the international search report:
22 March 2001

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

14

Applicant's or agent's file reference 82 073 a/sk		FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/EP00/02910	International filing date (day/month/year) 31/03/2000	Priority date (day/month/year) 01/04/1999	
International Patent Classification (IPC) or national classification and IPC C07K16/18			
Applicant FORSCHUNGSZENTRUM BORSTEL et al.			
<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 6 sheets, including this cover sheet.</p> <p><input checked="" type="checkbox"/> This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of 1 sheets.</p>			
<p>3. This report contains indications relating to the following items:</p> <ul style="list-style-type: none"> I <input checked="" type="checkbox"/> Basis of the report II <input type="checkbox"/> Priority III <input checked="" type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability IV <input type="checkbox"/> Lack of unity of invention V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement VI <input type="checkbox"/> Certain documents cited VII <input type="checkbox"/> Certain defects in the international application VIII <input type="checkbox"/> Certain observations on the international application 			
Date of submission of the demand 24/10/2000		Date of completion of this report 28.05.2001	
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465		Authorized officer Mennessier, T Telephone No. +49 89 2399 8687	



INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/EP00/02910

I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

Description, pages:

1-26 as originally filed

Claims, No.:

1-22,24 as originally filed

23 as received on 26/04/2001 with letter of 26/04/2001

Drawings, sheets:

1/1 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/EP00/02910

- ☐ the description, pages:
☐ the claims, Nos.:
☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application.
☒ claims Nos. 24.

because:

- ☒ the said international application, or the said claims Nos. 24 (with respect to industrial applicability) relate to the following subject matter which does not require an international preliminary examination (*specify*):
see separate sheet

- ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

- ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

- ☐ no international search report has been established for the said claims Nos. .

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

- ☐ the written form has not been furnished or does not comply with the standard.
☐ the computer readable form has not been furnished or does not comply with the standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/EP00/02910

1. Statement

Novelty (N)	Yes:	Claims	1-24
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-24
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1-23
	No:	Claims	

2. Citations and explanations **see separate sheet**

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/EP00/02910

1. Comments with respect to item III

Claim 24 is directed to a method of treatment by therapy, i.e., to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Article 34(4)(a)(i) PCT).

2. Comments with respect to item V

a) Document cited

Reference is made to the following document which is cited in the international search report:

D1: *Nucleic Acid Research*, 21(23), 1993, 5289-93

c) Novelty (Article 33(2) PCT)

None of the documents cited in the international search report discloses monoclonal antibodies to the human Mcm3. Therefore, it can be concluded that all the various claimed aspects of the invention as defined in claims 1-24 are new over the relevant state of the art.

d) Inventive step (Article 33(3) PCT)

- (i) Document D1 (see pages 5289 [Chapter "Antibodies"] and 5290 [Chapter "P1-related polypeptides in nuclear extracts" and Figure 1]), which is considered to represent the closest prior art, discloses the use of a rabbit antiserum directed against the most highly conserved part of the Mcm proteins to screen a human cDNA library. The blot shown in Figure 1 shows the P1 protein only, but not the other Mcm proteins.
- (ii) It is common knowledge that a great discrepancy exists between *in vitro* and *in situ* detection.

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/EP00/02910

- (iii) In view of the above remarks, it has to be considered that a person skilled in the art aware of document D1 and taken it into consideration alone or in combination with any of the other cited prior documents, would not have regarded it as obvious at the priority date to prepare hybridomas secreting monoclonal antibodies being capable of detecting and binding monospecifically human Mcm3 both immunohistologically and immunobiochemically.
 - (iv) Therefore, it appears that the technical problem posed by the provision of monoclonal antibodies as defined in either of claims 1 and 4 and also referred to in claim 6 would not have been solved by a person skilled in the art without the exercise of inventive skill.
 - (v) Consequently, it is considered that the claimed subject-matter as a whole involves an inventive step.
- e) Industrial applicability (Article 33(4) PCT)
- (i) The subject-matter of **claims 1-19, 21 and 22** is considered to be susceptible of industrial applicability.
 - (ii) For the assessment of the present **claims 20 and 24** on the question whether they are industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.

Application PCT/ EP 00702910
(No. 00 920 645.9-2116)

82703 m3/fg
26.04.2001

New claim 23

23. Diagnostic kit according to claim 22 for the combined detection of the expression of Mcm3, Ki-67 and p27 for tumour diagnostic.